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December 17, 2004

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

[Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504]

Dear Sir or Madam:

I am writing to comment on the Food and Drug Administration's proposed rule on *Salmonella* Enteritidis in shell eggs. I am a contract egg producer with an operation in Iowa. As a contract egg producer, I take pride in producing a safe product to deliver to my processor. Food safety is in my interest as a farmer, small business operator and consumer. Implementing these plans voluntarily with no federal mandate is to my advantage.

I am already regulated by many different federal and state agencies. Even when the aim of regulation is good, the burden of complying can be heavy, especially on farms and other small businesses. I respectfully urge FDA to minimize the additional burden in the following ways.

1. The FDA should thoroughly review all existing state and private egg quality assurance programs with the idea of incorporating these proven programs a part of proposed FDA regulations. Producers like me who voluntarily comply with one of these plans are then in compliance with FDA regulations.
2. Even though I am not a table egg producer I have a vested interest as taxpayer of minimizing inspection costs. The Agricultural Marketing Service already inspects egg packing facilities several times a year under the Shell Egg Surveillance Program, often in cooperation with state agencies. AMS and the states are knowledgeable of the egg industry, and using them will avoid diverting FDA employees away from homeland security, import inspections and other work.

I would also suggest that FDA needs more input from scientists who are experts in egg and poultry sciences. Several parts of the FDA proposal should be changed because they are either impractical, unnecessarily costly or in conflict with sound science.

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- The proposed rule does not include vaccination, even though it is a highly effective means of controlling SE. An effective vaccination program, combined with a single environmental test shortly before depopulation would allow our birds to have protection and allow control of SE.
- In our state, the laboratory system has not established a testing facility for SE. Before implementing the rule, FDA should survey public and private laboratories to assess whether lab capacity is adequate to test for SE. This survey would also apply for AI, and END as well.
- In winter months, it is not practical to wash our facilities. The birds have been removed which is the heat source, consequently the water lines will freeze. FDA should not impose a requirement that producers cannot carry out. FDA could make the wet cleaning optional, and require only a dry cleaning after an environmental positive. Vaccination could be used in conjunction with the dry cleaning thereby controlling the spread to a new flock.
- FDA is proposing a requirement that eggs held more than 36 hours must be refrigerated at 45° F. Our eggs are normally moved to the plant in less than 24 hours except on weekends and holidays. When the eggs are washed, there will be a higher incidence of checks and cracks if they have previously been refrigerated, simply because of the sudden change in temperature. In the summer our cooler is stretched to its limit to maintain 60 degrees. We believe a more realistic objective would be to require refrigeration at 55° F unless the eggs are held more than a week, and then impose the 45° F requirement for eggs held on the farm for more than seven days. Under normal operating situations, the eggs would be transferred to a processing plant within the seven day window. The science tells us that these times and temperatures are adequate.
- FDA's bio-security requirements should be more flexible. Bio-security is important. Some of the FDA requirements are not practical like the changing of clothes and shoes between houses. Our walkways are already constructed along the egg conveyor which travels through each house. The farm needs to establish its own bio-security steps.
- One other item is the requirement of a responsible person. I am the only person on the farm. I don't have time or the money to take several days for this kind of training especially as a contract breaking producer. My processor has technical people who are already doing this program on

other farms. Can this person be my technical liaison person as long as my records are maintained on the farm?

- What is going to happen to these SE positive eggs? If the positive eggs could not be sold at any price, then the loss to producers would be much more than FDA has estimated. Has the FDA addressed this problem through an indemnity system, payable if producers have fully complied with the regulatory requirements?
- For the bigger picture, these requirements could cause further consolidation in our industry, with smaller operations unable to afford the additional labor and compliance costs. Our government yet always professes to be concerned about the increasing concentration in agriculture.

In closing, I repeat that my farm is dedicated to delivering a safe product to our processor. We will always comply with the law and regulations to the best of our ability. We need regulations that are flexible, reasonably applied, and scientifically based if we are to survive as a business. In agriculture, we usually cannot pass on increased costs since we are the end. The producer ends up absorbing the cost of regulations. I strongly urge you to make the appropriate changes so this regulation can be workable for our industry.

Sincerely,

A handwritten signature in black ink, appearing to read 'James R. Dean', with a stylized flourish at the end.

James R. Dean  
Center Fresh Egg Farm L.L.P.